UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,348	09/26/2001	Wolfram Steinhilber	24702	2818

20529 7590 12/15/2004

NATH & ASSOCIATES
1030 15th STREET, NW
6TH FLOOR
WASHINGTON, DC 20005

EXAMINER	
SCHNIZER, HOLLY G	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/889,348	STEINHILBER ET AL.	
	Examiner	Art Unit	
	Holly Schnizer	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-13 and 15-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-11,13 and 15-17* is/are rejected.

7)☒ Claim(s) *12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 September 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-4, and 14 have been cancelled. Claims 5-13 and 15-17 are pending and have been considered in this Office Action.

Priority

The examiner acknowledges the amendment inserting the priority statement in the first line of the Specification.

Objection to Specification Withdrawn

The objection to the Specification for lack of an abstract is withdrawn in light of the amendment adding the abstract.

Rejections Withdrawn

The rejections of Claims 1-17 under 35 U.S.C. 112, second paragraph are withdrawn in light of the amendments.

The rejection of Claims 1-3, 5-11, 13-14, and 16-17 under 35 U.S.C. 102(a) as being anticipated by LeVine et al. is withdrawn in light of the amendments . Levine et al. does not teach that the SP-A contained in the composition taught therein was recombinantly produced or that lipids were removed. Thus, the composition of LeVine et al. does not appear to be "lipid-free".

The rejection of Claims 1-4 and 13-15 under 35 U.S.C. 102(b) as anticipated by Kido et al. is withdrawn in light of the amendments. Kido et al. teaches a method of treating pulmonary viral infection with lung surfactant and therefore the SP-A contained therein is not considered to be lipid-free.

The rejection of Claims 1-3 and 16-17 under 35 U.S.C. 102(e) as being anticipated by Schilling et al. is withdrawn in light of the amendments and Applicants arguments.

The rejection of Claims 1-17 under 35 U.S.C. 103(a) as being obvious over McCormack et al. and Borron et al. in view of Madan et al., LeVine et al., King et al, and Schilling et al. is withdrawn. Only Borron et al. teaches recombinant production of SP-A without adding lipids to the composition. Schilling et al. teaches that the SP-A compositions obtained therein should be combined with lipids to form a complex for use in treating respiratory diseases (Col. 7, lines 61-Col. 8). Therefore, Schilling et al. teaches away from the claimed method of treatment using a "lipid-free" composition of recombinant SP-A.

Rejections Maintained

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claims 5, 10, 11 and 16 are rejected under 35 U.S.C. 102(a) as anticipated by Borron et al. This rejection is set forth in the prior Office Action, mailed on 6/22/04.

Applicants argue that any compositions that may be taught by Borron et al. do not contain recombinantly prepared SP-A and that the relevant section of Borron et al. that discusses recombinant SP-A does not teach a pharmaceutical composition as presently claimed in claim 5 but only discusses the generation of recombinant SP-A alone by using insect cell lines.

This argument has been considered but is not deemed persuasive for the following reasons. As stated in the previous Office Action, Borron et al. teach a composition comprising a purified recombinant SP-A that is lipid-free and contained in buffer (considered a carrier) at neutral pH (p. L680, Col. 2, last two paragraphs; indicates that recombinant SP-A was dialyzed against Tris buffer at pH 7.4). Also, as stated in the previous Office Action, the claims are drawn to a product with an intended use. However, without evidence that the intended use changes the product, the intended use is not considered because it is the product being claimed and not the method of using it. Therefore, while Borron et al. does not use the disclosed composition in a method of treatment, absent evidence to the contrary, the disclosed composition identical to the composition presently claimed. Moreover, the recombinant SP-A in the composition of Borron et al. appears to be patentably indistinguishable from recombinant SP-A obtainable by expression of a genomic sequence or by expression of a cDNA. Thus, the claims are rejected for reasons given above and in the previous Office Action.

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-9, 13, 15, 16, and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treatment of pulmonary infection or inflammation using recombinant SP-A or articles of manufacture as claimed that contain a package insert indicating that the active component is useful for treatment of pulmonary infection or inflammation, does not reasonably provide enablement for methods of preventing pulmonary infection or inflammation or articles of manufacture which indicate that pulmonary infection or inflammation can be prevented using the SP-A composition of the invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d, 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). These factors include (1) quantity of experimentation, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Breadth of the Claims

The claims encompass method of preventing pulmonary infection and inflammation and articles of manufacture that indicate that such infections and inflammation may be prevented using the SP-A composition of the invention.

Nature of the Invention

The nature of the invention involves the recombinant expression and purification of SP-A and the use of lipid free formulations of recombinant SP-A in the treatment of pulmonary infection and inflammation. Infection and inflammation involve cascades of different protein activities and interactions and are highly complex events.

The amount of direction and guidance presented

The Specification does not provide any guidance as to how "lipid-free" formulations of SP-A can be used to "prevent" infection or inflammation. "Infection" has been interpreted to mean entry of the infecting agent (bacterial or viral) into the cell.

Presence or Absence of Working examples

The present Specification does not provide any examples of a method of "preventing" any infection or inflammatory activity. The examples show that while the SP-A compositions taught therein were effective in "clearing" group B streptococcal infection upon co-administration of the bacteria with the SP-A composition, the SP-A composition did not "prevent" bacterial infection (see Fig. 1 at 6 hours after co-administration).

State of the Prior Art and Relative Skill of those in the art:

The prior art does not teach or suggest any methods of "preventing" invention or inflammation using any type of SP-A composition.

Predictability or unpredictability of the art

In light of the lack of knowledge concerning the use of SP-A compositions to "prevent" pulmonary infection or inflammation and in view of the great complexity of the infection and inflammation processes, the determination of what type of SP-A composition could possibly prevent these processes is highly unpredictable.

Quantity of Experimentation

The claimed method of preventing inflammation or infection is not a routine method practiced with a new SP-A formulation—preventing inflammation or infection by any pathogen any has never been achieved. The specification and prior art lack any evidence that the SP-A formulations disclosed in the Specification could prevent any pulmonary infection or inflammatory event. Thus, practicing the present invention commensurate in scope with the claims would not merely require repetition of what has been described in the Specification, but an inventive contribution on the part of the practitioner to determine how to change the compositions disclosed in the present Application so that they could be used to prevent pulmonary infection or inflammation, if it is even possible. Thus, the full scope of the claim is not considered enabled.

This rejection could be overcome by deleting "preventing or" in the rejected claims.

Claim Objections

Claim 12 is objected to for depending from a rejected claim but would be allowable if rewritten in independent form including all of the limitations of the claims from which it depends.

Conclusions

No Claims are allowable. Claims 5-11, 13, and 15-17 are rejected and Claim 12 is objected to. The prior art of record does not teach or suggest a method of treating pulmonary infection or inflammation by administering a "lipid-free" composition comprising recombinant SP-A or a "lipid-free" pharmaceutical composition comprising recombinant SP-A and SP-D.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (571) 272-0958. The examiner can normally be reached on Monday through Wednesday from 8 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Holly Schnizer
December 12, 2004

JON WEBER
SUPERVISORY PATENT EXAMINER